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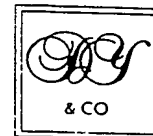
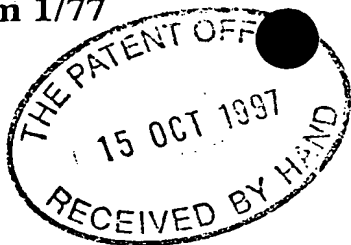
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2. Patent application number
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15 OCT 1997

9721863.0

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(underline all surnames)

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Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

7304512001

4. Title of the invention

ANKLE-FOOT ORTHOSIS

5. Name of your agent (if you have one)

D YOUNG & CO

"Address for service" in the United Kingdom to which all correspondence should be sent
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Description 9

Claims(s) 4

Abstract 1

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ANKLE-FOOT ORTHOSIS

This invention relates to ankle-foot orthoses.

5

Orthoses are mechanical devices which impose forces upon a limb of a patient and can be used for a variety of different purposes. For example, orthoses may be provided for supportive, functional, corrective or protective purposes, or for a combination of these. Ankle-foot orthoses are typically provided to provide protection
10 to the ankle and foot of a patient as well as to provide support against excessive plantarflexion or dropping of the foot. In addition to this resistive function, they may also be employed to assist dorsiflexion of the patient's foot during the push off phase of the patient's gait.

15

Foot plantarflexion is a medical condition that can arise from a variety of causes, for example disease or congenital abnormality. Patients affected by this condition typically experience difficulty in walking as they must lift their foot excessively from the ground in order to avoid stumbling.

20

A variety of different ankle-foot orthoses have previously been proposed for resisting plantarflexion, and in some cases for additionally assisting dorsiflexion. Figures 1a, 1b, 2a and 2b illustrate two of these previously proposed devices.

25

Figure 1a illustrates one previously proposed ankle-foot orthosis before it is assembled on a patient. The orthosis 10 must be used in conjunction with a shoe 12 that provides close contact between the shoe and the foot in the region of the instep. The orthosis 10 comprises a pair of supporting metal uprights 14, one connected to either side of the shoe 12 in the region of the heel 16. The connections each comprise a plantarflexion stop 18 that resists foot drop and may also include springs (not
30 shown) to assist dorsiflexion. The upper ends of the uprights are connected to a supporting strap 20 which is securable about the patient's calf. With reference to

Figure 1b, it can be seen that the supporting strap 20 provides support about the patient's calf, and that the plantarflexion stops 18 and shoe 12 provide support under the foot of the patient to resist plantarflexion.

5 Figures 2a and 2b illustrate another previously proposed orthosis device which must also be used in conjunction with a shoe that provides close contact between the shoe and the foot in the region of the instep. In this example, the orthosis 22 comprises a one-piece plastics moulding 24 which comprises a calf abutting region 26 and a sole abutting region 28. The top of the calf abutting region 26 is provided with
10 a closure mechanism 27 that enables the device to be secured to the calf of a patient. The sole abutting region 28 acts in conjunction with the shoe 30 to support the foot of the patient. The stiffness of the plastics moulding and the shape thereof in the region of the ankle defines the amount of resistance to plantarflexion. If more resistance is required, then the gap across the front of the ankle can be reduced, or the
15 stiffness of the plastics can be increased.

Both of the aforementioned previously proposed devices adequately support the foot of a patient to resist plantarflexion. However, they both exhibit serious deficiencies that make them highly unpopular with patients.

20

A first disadvantage is that both of the previously proposed orthoses are large bulky devices which are clearly visible when worn. Thus, the patient's illness or abnormality is immediately apparent to others and this can adversely affect the patient's state of mind. This problem can be particularly apparent with child patients
25 as the orthosis is an immediately obvious difference which other children can ridicule. It can also be a serious problem for adult patients as a visible device immediately labels them as a disabled or abnormal person with corresponding ramifications for their personal and working lives.

30

A further disadvantage is that both of these previously proposed devices must be worn with shoes. Thus, if a patient wished to walk without shoes or to go

swimming, for example, then they would have to do so without any means for resisting plantarflexion.

5 A further disadvantage is that these previously proposed devices can cause extreme discomfort when worn. This problem is particularly apparent with the orthosis of Figures 2a and 2b as the device extends under the foot of the patient and thus the full weight of the patient bears upon the device when the patient walks.

10 Yet another disadvantage is that both of these previously proposed devices are difficult and time consuming to put on and take off. Furthermore, the second device often requires the fabrication of special shoes as it is often not possible to fit the device within normal off-the-shelf shoes. Finally, both devices are expensive to make and fit as they must be closely fitted to the feet and legs of the patient, and as they are made from relatively expensive materials.

15

It is an object of aspects of the invention to alleviate some or all of these disadvantages.

20 In accordance with the invention, there is provided an ankle-foot orthosis for resisting plantarflexion of a patient's foot, the orthosis comprising: a resiliently flexible sock-like structure enveloping, in use, at least a portion of a patient's lower leg in the vicinity of the ankle and at least a portion of the plantar and dorsal aspects of the patient's foot.

25 Thus, this aspect of the invention provides a discrete arrangement which adequately resists plantarflexion without requiring the patient to wear a shoe.

30 Preferably the orthosis comprises a reinforcing means for further resisting planterflexion of the foot. The reinforcing means may be a length of tape, the ends of the tape being joined together to form a figure-of-eight passing under the instep, behind the ankle and crossing on the dorsal aspect of the foot. Alternatively, the

reinforcing means may comprises a rib running along at least a portion of the dorsal aspect of the foot and substantially midway between the medial malleolus and the lateral malleolus. Preferably the reinforcing means has a greater resilience than the sock-like structure.

5

The sock-like structure may be defined by the rib and a pair of straps, one secured to either end of the rib and respectively securable about the plantar aspect of the foot and the portion of the patient's lower leg in the vicinity of the ankle.

10

Preferably, the orthosis comprises an insertion slit extending midway between the medial malleolus and the lateral malleolus towards the calcaneum, means being provided to securely close the slit once the patient's foot has been inserted in the orthosis.

15

The closing means may comprise a mechanical hook and loop fastener, a set of hoops or hooks being provided adjacent one edge of the slit and a corresponding set of hooks or hoops being provided on a closure member affixed to the other side of the slit, respective hooks and loops being connectable to securely close the slit. Alternatively, the closing means may comprise a zip fastener secured to opposite sides of the slit. As a further alternative, the closing means may comprise a set of eyelets closable by a lace.

20

Preferably, the orthosis envelops the dorsal and plantar aspects of the foot without enveloping the toes. Preferably, the orthosis envelops the plantar aspect of the foot without enveloping the calcaneum. The orthosis could envelop the calcaneum if, for example, mechanical correction of the heel bone is required. The device may also be contoured on the surface abutting, in use, the plantar aspect of the foot to aid support of the metatarsals and to position the foot correctly.

25

30

Preferably, the sock-like structure is of silicone. Preferably, the sock-like structure is a 35 shore silicone elastomer, or a higher or lower shore silicone

elastomer. Preferably, the reinforcing means is of silicone.

5 Preferably, the orthosis is skin coloured and/or fabricated by injection moulding. The orthosis could alternatively be brightly coloured so as to appeal to children.

10 In accordance with a second aspect of the invention, there is provided a kit comprising a plurality of orthoses as described herein, the orthoses being of varying size and shape for fitting to feet of different sizes and shapes. The kit may also comprise differently coloured orthoses to allow the matching of the colour of the orthosis to the skin colour of the patient.

15 In accordance with a third aspect of the invention, there is provided an ankle-foot orthosis for resisting plantarflexion of a patient's foot, the orthosis comprising: a resilient rib locatable, in use, along and in abutment with at least a portion of the dorsal aspect of the patient's foot and at least a portion of the patient's lower leg, the orthosis comprising means for securing the rib to the patient's foot and lower leg.

20 In one embodiment, the securing means comprises a first strap means securable about one end of the rib and the patient's lower leg, and a second strap means securable about the other end of the rib and the patient's foot.

25 In another embodiment, the securing means comprises a first strap means securable about one end of the rib and the patient's lower leg and a shoe for securing the other end of the rib to the patient's foot.

In another embodiment, the securing means comprises an adhesive, at least end portions of the rib being adhered to the patient's lower leg and foot.

30 In any event, it is preferred that the rib is of polypropylene.

Embodiments of the present invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figures 1a and 1b are schematic representations of one previously proposed orthosis;

5 Figures 2a and 2b are schematic representations of another previously proposed orthosis;

Figure 3 is a schematic representation of an orthosis according to a first aspect of the invention; and

10 Figure 4 is a schematic representation of an orthosis according to a second aspect of the invention.

With reference to Figure 3, the orthosis 32 comprises a resiliently flexible sock-like structure 34 and a reinforcing means 36 (shown in ghost), which in this embodiment is a tape 38 - the ends of which are joined together to form a figure-of-eight which passes under the instep, behind the ankle and crosses on the dorsal aspect of the foot. The reinforcing means may be formed integrally with the sock-like structure or, alternatively, the reinforcing means may be formed separately and subsequently inserted within the sock-like structure.

20 The resilience of the sock-like structure and the reinforcing means are chosen, and may be varied, in dependence upon the degree to which the patient suffers from plantarflexion. Indeed, the reinforcing means 36 can be dispensed with if sufficient resistance to plantarflexion is provided by the sock-like structure 34. It is preferred for the resilience of the reinforcing means 36, if provided, to be greater than that of
25 the sock-like structure 34.

In this embodiment, the orthosis 32 envelops a portion of the patients lower leg which preferably includes the medial malleolus 40 (the inside of the ankle) and the lateral malleolus 42 (the outside of the ankle), the calcaneum 44 (the heel), a portion of the plantar aspect 46 of the foot (the sole of the foot) and a portion of the dorsal
30 aspect 48 of the foot (the back of the foot). In this embodiment, the toes 49 of the

foot are not enveloped by the orthosis, although they could be enveloped if desired. It is preferred that the orthosis extends beyond the medial and lateral malleoli.

5 The sock-like structure 34 is provided with a slit (not shown) which extends in a direction towards the calcaneum between the medial and lateral malleoli. In this embodiment, the slit is closable by a mechanical hook and loop fastener 50, such as velcro®. One portion of the fastener (ie. either a hook portion or a loop portion) is affixed to one side of the slit. The other portion of the fastener 50 is affixed to a strap 52 that is affixed to the other side of the slit.

10

Figure 4 shows a second embodiment of the invention wherein the orthosis 32 is provided with a zip fastener 54, respective parts of which are secured to either side of the slit. In this embodiment, the sock-like structure 34 does not envelop the calcaneum 44 of the foot. It has been found that the orthosis 32 can be made
15 significantly more comfortable if both the calcaneum 44 and toes 49 are not enveloped by the sock-like structure 34. In this embodiment, the reinforcing means comprises a rib 56 which extends partway along the dorsal aspect of the foot. The rib may be formed integrally with the orthosis. Alternatively, the rib may be removably insertable into a pocket provided on the dorsal aspect of the foot to allow for the stiffness of the
20 rib, and/or the angle of support (by inserting differently shaped ribs), to be changed if desired.

The orthosis of either embodiment may be coloured so that it can be matched to the skin colour of the patient, and may be provided in a variety of different sizes
25 and shapes. The orthosis is preferably manufactured by injection moulding. Alternatively, the orthosis may be manufactured by milling (as described below) and subsequently building up layers of the device upon a suitable cast.

The orthosis may be of a variety of different materials chosen to have a
30 suitable resilience. For example, the orthosis could be of rubber, silicone, plastics or of any other material apparent to persons skilled in the art. Preferably the orthosis is

of 35 shore silicone elastomer. The orthosis may be of a greater or lesser shore value depending upon the particular needs of the patient to which it is to be fitted. The reinforcing means may be of silicone, with a chosen shore value, or may be of any other material apparent to persons skilled in the art. The reinforcing means could be
5 of the same material as the sock-like structure, or could be of a different material. For example, in the arrangement of Figure 4, the rib may be of a metal.

Two suitable elastomers are sold under the product names HCR9960 and MED4035 by Nusil Technology of 1050 Cindy Lane, Carpinteria, California, USA.
10 HCR9960 has a working time of approximately 12 hours and MED4035 has a shorter working time of approximately 3 to 4 hours, after which the elastomer cures. The elastomers are thermo-setting and are strained through a 200 mesh screen to remove particulate contaminants.

15 The elastomers are supplied as A and B components which are preferably combined in equal portions on a two roll mill, or other suitable device, prior to use. A suggested sequence for blending the two components is to first soften part B on the mill and then soften part A, after which an equal weight of part B should be added to part A and then thoroughly mixed. At this stage, it is recommended to keep the
20 temperature of the material as low as possible so as to maximise the table life of the elastomer. The mixture may then be manually fitted to a plaster cast of a patient's foot, or more preferably supplied to injection moulding apparatus to mould a suitably shaped orthosis. Curing of the blended elastomer may be accelerated by heat and can take from 3 to 4 hours. The cure may be inhibited by any ambient traces of organic
25 rubbers and other substances and thus it is preferred for the fabrication of the orthosis to be conducted in a thoroughly cleaned area.

It will be understood, of course, that the invention has been described herein by way of example only and that modifications may be made within the scope of the
30 invention.

For example, as a variation to the second embodiment, the orthosis may comprise a reinforcing means moulded from polypropylene, for example, which is worn along the dorsal aspect of the patient's foot. A pair of straps are provided, one connected to either end of the reinforcing member. Securing the straps, respectively,
5 around the base of the foot and the back of the ankle secures the orthosis to the foot of the patient to resist planterflexion. This arrangement would be particularly advantageous for warmer climates as the majority of the patient's foot is not covered by the orthosis. In this example, the "sock-like structure" would comprise the reinforcing means and the pair of straps.

10

A further modification of this arrangement only suitable for use in conjunction with a shoe, would comprise an orthosis that has a reinforcing means of polypropylene, for example, and a single strap provided at the end of the reinforcing means closest to the ankle of the patient, in use. Securing the strap around the ankle
15 of the patient and inserting the foot and reinforcing means within a shoe provides an orthosis that is capable of resisting plantarflexion of the patient's foot.

A yet further modification would comprise a resilient rib of polypropylene, for example, that is shaped to fit against at least a portion of the patient's lower leg and
20 at least a portion of the dorsal aspect of the patient's foot, and then adhered at least at the ends thereof to the Patient's lower leg and foot. The adhesive could be any adhesive suitable for bonding articles to skin.

Suitable materials other than polypropylene will be immediately apparent to
25 persons skilled in the art.

CLAIMS

1. An ankle-foot orthosis for resisting plantarflexion of a patient's foot, the orthosis comprising: a resiliently flexible sock-like structure enveloping, in use, at least a portion of a patient's lower leg in the vicinity of the ankle and at least a portion of the plantar and dorsal aspects of the patient's foot.
2. An orthosis according to Claim 1, comprising a reinforcing means for further resisting planterflexion of the foot.
3. An orthosis according to Claim 2, wherein the reinforcing means comprises a length of tape, the ends of the tape being joined together to form a figure-of-eight passing under the instep, behind the ankle and crossing on the dorsal aspect of the foot.
4. An orthosis according to Claim 2, wherein the reinforcing means comprises a rib running along at least a portion of the dorsal aspect of the foot and substantially midway between the medial malleolus and the lateral malleolus.
5. An orthosis according to Claim 4, wherein the sock-like structure is defined by the rib and a pair of straps, one secured to either end of the rib and respectively securable about the plantar aspect of the foot and the portion of the patient's lower leg in the vicinity of the ankle.
6. An orthosis according to any of Claims 2 to 5, wherein the reinforcing means has a greater resilience than the sock-like structure.
7. An orthosis according to any of Claims 1 to 6, comprising an insertion slit extending susbtantially midway between the medial malleolus and the lateral malleolus at the back of the ankle towards the calcaneum, means being provided to securely close the slit once the patient's foot has been inserted in the orthosis.

8. An orthosis according to Claim 7, wherein the closing means comprises a mechanical hook and loop fastener, a set of hoops or hooks being provided adjacent one edge of the slit and a corresponding set of hooks or hoops being provided on a closure member affixed to the other side of the slit, respective hooks and loops being connectable to securely close the slit.
9. An orthosis according to Claim 7, wherein the closure member comprises a zip fastener secured to opposite sides of the slit.
10. An orthosis according to Claim 9, wherein the closure member comprises a set of eyelets provided on either side of the slit, the slit being closable by a lace fed through the eyelets.
11. An orthosis according to any preceding claim, wherein the orthosis envelops at least a portion of the dorsal and plantar aspects of the foot without enveloping the toes.
12. An orthosis according to any preceding claim, wherein the orthosis envelops at least a portion of the plantar aspect of the foot without enveloping the calcaneum.
13. An orthosis according to any preceding claim, wherein the sock-like structure is of silicone.
14. An orthosis according to Claim 13, wherein the sock-like structure is a 35 shore silicone elastomer.
15. An orthosis according to Claim 2 and to any of Claims 3 to 14 when dependent upon claim 2, wherein the reinforcing means is of silicone.
16. An orthosis according to Claim 2 and to any of Claims 3 to 14 when dependent upon claim 2, wherein the reinforcing means is of a different material to that of the

sock-like structure.

17. An orthosis according to any preceding claim, wherein the orthosis is skin coloured.

5

18. An orthosis according to any preceding claim, wherein the orthosis is fabricated by injection moulding.

10

19. A kit comprising a plurality of orthoses according to any preceding claim, the orthoses being of varying size and shape for fitting to feet of different sizes and shapes.

15

20. A kit according to Claim 19, comprising differently coloured orthoses to allow the matching of the colour of the orthosis to the skin colour of the patient.

20

21. An ankle-foot orthosis for resisting plantarflexion of a patient's foot, the orthosis comprising: a resilient rib locatable, in use, along and in abutment with at least a portion of the dorsal aspect of the patient's foot and at least a portion of the patient's lower leg, the orthosis comprising means for securing the rib to the patient's foot and lower leg.

25

22. An orthosis according to Claim 21, wherein the securing means comprises a first strap means securable about one end of the rib and the patient's lower leg, and a second strap means securable about the other end of the rib and the patient's foot.

30

23. An orthosis according to Claim 21, wherein the securing means comprises a first strap means securable about one end of the rib and the patient's lower leg and a shoe for securing the other end of the rib to the patient's foot.

24. An orthosis according to Claim 21, wherein the securing means comprises an adhesive, at least end portions of the rib being adhered to the patient's lower leg and

foot.

25. An orthosis device according to any of Claims 21 to 24, wherein the rib is of polypropylene.

5

26. An orthosis substantially as hereinbefore described with reference to Figures 3 and 4 of the accompanying figures.

27. A kit substantially as hereinbefore described.

ABSTRACT**ANKLE-FOOT ORTHOSIS**

5

An ankle-foot orthosis 32 for resisting plantarflexion of a patient's foot, the orthosis 32 comprising: a resiliently flexible sock-like structure 34 enveloping, in use, at least a portion of a patient's lower leg in the vicinity of the ankle and at least a portion of the plantar 46 and dorsal 48 aspects of the patient's foot.

10

FIGURE 3

FIGURE 1a

1/2

FIGURE 1b

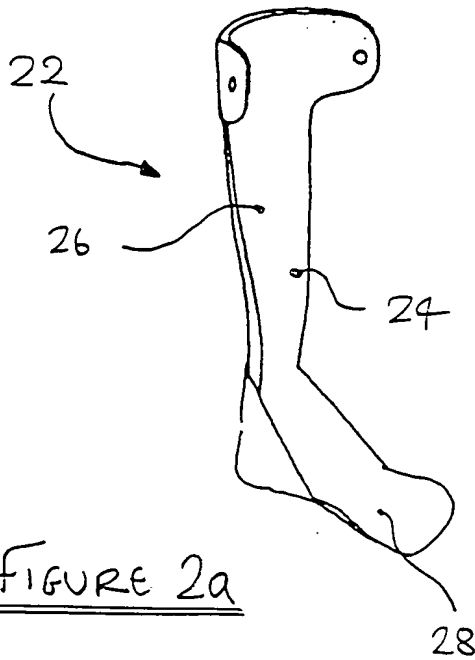
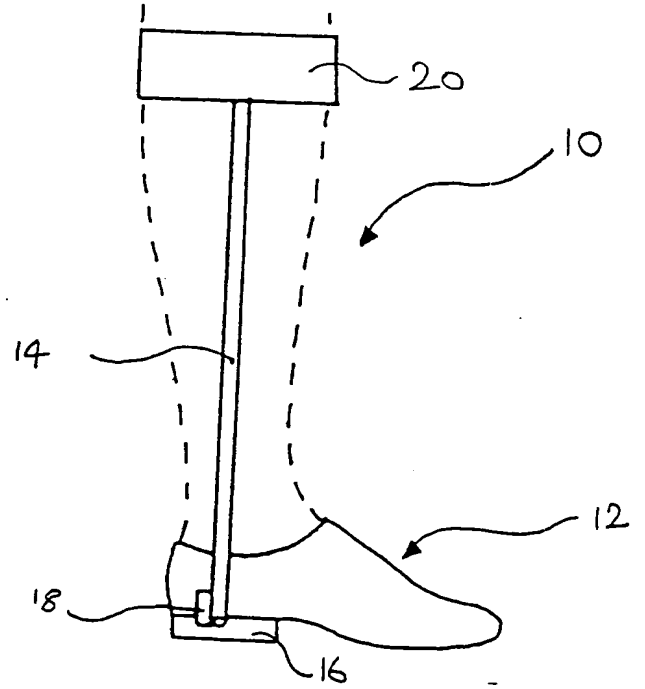
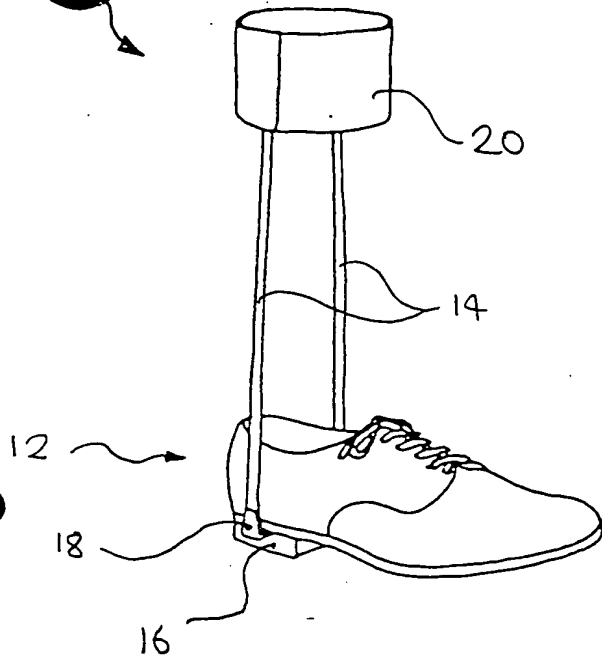


FIGURE 2a

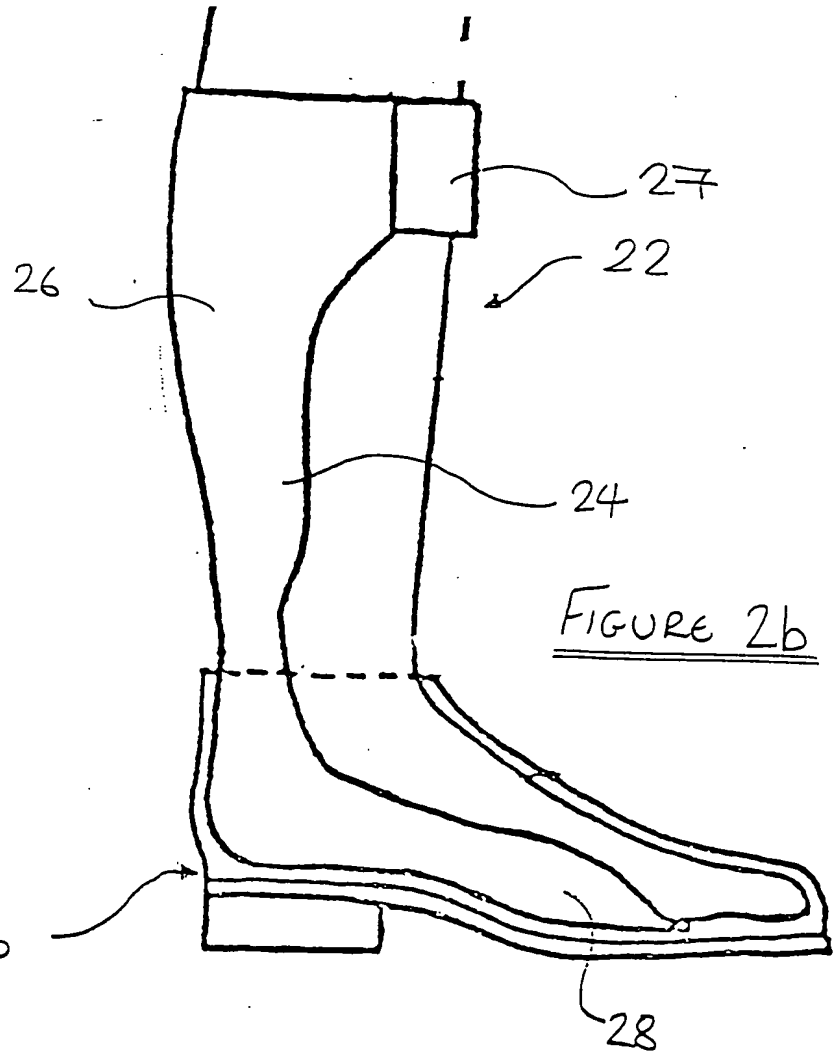


FIGURE 2b

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FIGURE 3

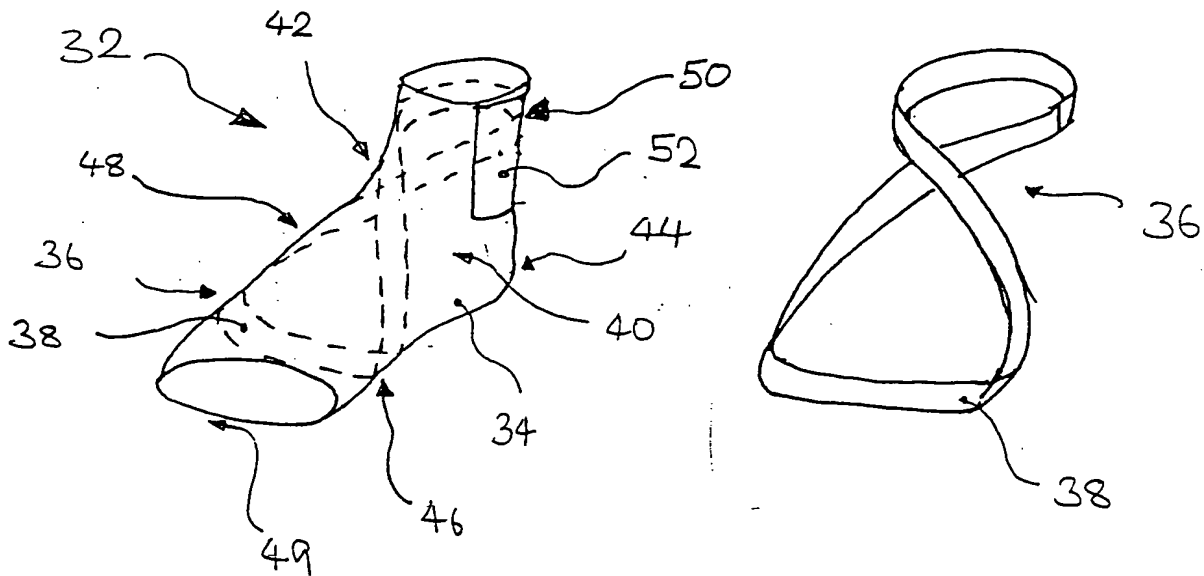
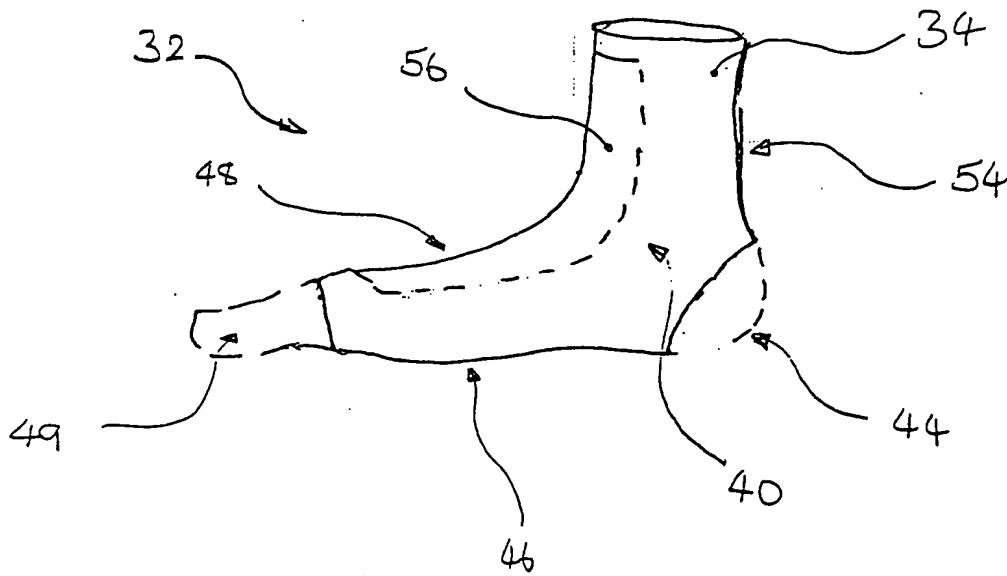


FIGURE 4



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